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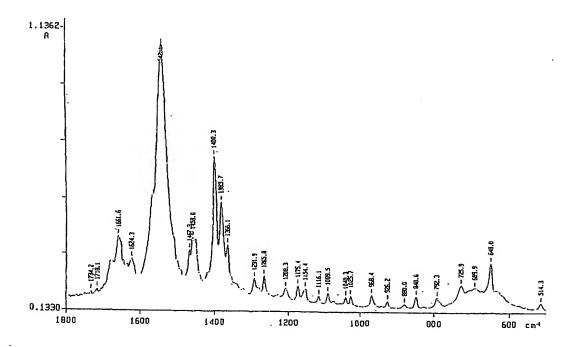
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### (54) Title: PROCESS FOR THE PREPARATION OF GABAPENTIN FORM-II



(57) Abstract: The present invention relates to a new industrial feasible process for the preparation of Gabapentin Form-II via a novel intermediate Gabapentin hemisulphate hemihydrate with out forming Gabapentin Form-III by neutralizing the Gabapentin hemisulphate hemihydrate solution with a base at higher temperatures followed by cooling to yield Gabapentin Form II with sulphate ions less than 100 ppm with respect to Gabapentin.



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#### **Declarations under Rule 4.17:**

as to applicant's entitlement to apply for and be granted a patent (Rule 4.17(ii)) for the following designations AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW, ARIPO patent (BW, GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT,

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C. DOCUM	MENTS CONSIDERED TO BE RELEVANT				
Category*	Citation of document, with indication, where a	ppropriate, of the relevant passages	Relevant to claim No.		
Α	WO 1998/028255 A (TEVA PHARM (02.07.1998) claims 1-7; examples 13,16 (cited in t	MA) 2 July 1998 he application).	1-18		
	-	•			
Α	US 2004068011 A1 (CANNATA V et (08.04.2004) example 1, par. 20-23.	al.) 8 April 2004	1-18		
		·	•		
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Patent document cited in search report			Publication date	Patent family member(s)			Publication date
us 1	A	20040680 11	2004-04-08	ES JP DE	A T	2206078 2004512321T 10196805T	2004-05-01 2004-04-22 2004-04-15
				IT	A	MI20002285	2002-04-23
				IT	В	1319234	2003-09-26